MAY 0 3 2002

**510(k) Summary**
**IRIDEX Corporation**
**IRIS Medical® OcuLight® SL/SLx** K020374 1/3

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

John D'Angelo
IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043
(650) 962-8848 ext. 3905

Contact Person: (same as above)

Date Prepared: April 23, 2002

**Name of Device and Name/Address of Sponsor**

IRIS Medical OcuLight SL/SLx

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043

**Classification Name**

Laser Instrument, Surgical, Powered
CFR Section: 886.4390
Product Code: HQF

**Predicate Devices**

The OcuLight SL/SLx laser systems for the expanded indication of iridotomy are substantially equivalent to other currently legally marketed ophthalmology laser devices including IRIDEX Corporation's IRIS Medical OcuLight SL/SLx Laser Photocoagulators (K894841 and K913430), the IRIS Medical OcuLight GL Laser Photocoagulator (K960971), the Keeler Instruments, Microlase (K890086), and the Nidek, DC-3300 Laser Diode Photocoagulation (K013760).

**Device Description**

The OcuLight SL/SLx is a semiconductor diode laser system that delivers pulsed infrared 810 nm laser light intended to be used for the indication of retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, and other laser diode treatments. Visible red (630-650 nm) semiconductor diode laser is used for aiming.

**Intended Use**

The OcuLight SL/SLx is indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, and other diode laser treatments. The following are examples of applications for the OcuLight SL/SLx laser systems.

| Condition | Treatment |
|---|---|
| Diabetic Retinopathy<br>• Nonproliferative Retinopathy<br>• Macular Edema<br>• Proliferative Retinopathy | Panretinal Photocoagulation (PRP); Focal and Grid Laser Treatments |
| Glaucoma<br>• Primary Open Angle<br>• Closed Angle<br>• Refractory Glaucoma (recalcitrant/uncontrolled) | Laser Trabeculoplasty; Iridotomy; Transscleral Cyclophotocoagulation (TSCPC) |
| Retinal Tears, Detachments, and Holes | Transscleral Retinal Photocoagulation (TSRPC); Focal and Grid Laser Treatments |
| Lattice Degeneration | PRP; Focal and Grid Laser Treatments |
| Age-related Macular Degeneration (AMD) | Focal and Grid Laser Treatments |
| Intra-Ocular Tumors<br>• Choroidal Hemangioma<br>• Choroidal Melanoma<br>• Retinoblastoma | Focal and Grid Laser Treatments |
| Retinopathy of Prematurity | PRP; TSRPC; Focal and Grid Laser Treatments |
| Sub-Retinal (choroidal) Neovascularization | Focal and Grid Laser Treatments |
| Central and Branch Retinal Vein Occlusion | PRP; Focal and Grid Laser Treatments |

**Technological Characteristics and Substantial Equivalence**

The OcuLight SL/SLx Laser System is indicated for retinal photocoagulation, laser trabeculoplasty, TSCPC, and TSRPC. The expansion of the indications for use for the proposed OcuLight does not result in a change to the hardware or firmware for the currently marketed OcuLight.

The OcuLight GL Laser System is indicated for retinal photocoagulation and laser trabeculoplasty. The OcuLight GL is a semiconductor-based ophthalmic laser photocoagulator that delivers true continuous wave green laser (532 nm) light.

The OcuLight GL delivers similar power, use similar delivery devices, and have similar indications as the OcuLight SL/SLx.

The Keeler Instruments Microlase Diode Laser System is indicated for retinal photocoagulation. The Microlase diode laser system delivers a wavelength of 780 to 840 nm infrared laser light.

The Microlase delivers the same infrared wavelength, pulses of equivalent duration, treatment spots of equivalent size, and energy densities equivalent to the OcuLight SL/SLx.

The Nidek DC-3300 Laser Diode Photocoagulation is indicated for all retinal photocoagulation procedures. The DC-3300 and OcuLight SL/SLx use a variety of delivery systems, including slit lamps, indirect ophthalmoscopes, endoprobes, and transscleral probes.

The DC-3300 delivers a similar infrared wavelength, pulses of equivalent duration, treatment spots of equivalent size, and energy densities equivalent to the OcuLight SL/SLx.

**Non-Clinical performance Data**

None

**Clinical performance Data**

None

**Conclusion**

The OcuLight SL/SLx is substantially equivalent to predicate devices currently legally marketed for the indication of retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, and other diode laser treatments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 3 2002

Mr. John D'Angelo
Vice President, Regulatory Affairs
and Quality Assurance
IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, California 94043

Re: K020374
Trade/Device Name: IRIS Medical® OcuLight® SL/SLx
Regulation Number: 886.4390 and 878.4810
Regulation Name: Ophthalmic laser and laser surgical instrument
Regulatory Class: II
Product Code: HQF and GEX
Dated: January 30, 2002
Received: February 4, 2002

Dear Mr. D'Angelo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Pending K020374

Device Name: IRIS Medical® OcuLight® SL/SLx

Indications For Use:

The IRIDEX OcuLight SL/SLx is indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, and other diode laser treatments. The following are examples of applications for the OcuLight SL/SLx laser systems.

| Condition | Treatment |
|---|---|
| Diabetic Retinopathy<br>• Nonproliferative Retinopathy<br>• Macular Edema<br>• Proliferative Retinopathy | Panretinal Photocoagulation (PRP); Focal and Grid Laser Treatments |
| Glaucoma<br>• Primary Open Angle<br>• Closed Angle<br>• Refractory Glaucoma (recalcitrant/uncontrolled) | Laser Trabeculoplasty; Iridotomy; Transscleral Cyclophotocoagulation (TSCPC) |

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020374

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

# INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Pending~~ K020374

Device Name: IRIS Medical® OcuLight® SL/SLx

Indications For Use:

| Condition | Treatment |
|---|---|
| Retinal Tears, Detachments, and Holes | Transscleral Retinal Photocoagulation (TSRPC); Focal and Grid Laser Treatments |
| Lattice Degeneration | PRP; Focal and Grid Laser Treatments |
| Age-related Macular Degeneration (AMD) | Focal and Grid Laser Treatments |
| Intra-Ocular Tumors<br>• Choroidal Hemangioma<br>• Choroidal Melanoma<br>• Retinoblastoma | Focal and Grid Laser Treatments |
| Retinopathy of Prematurity | PRP; TSRPC; Focal and Grid Laser Treatments |
| Sub-Retinal (choroidal) Neovascularization | Focal and Grid Laser Treatments |
| Central and Branch Retinal Vein Occlusion | PRP; Focal and Grid Laser Treatments |

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020374

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)